# dardes User Manual

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# Preface

This brief user's manual was designed to help users familiarise themselves with the basic functionality of the *dardes* system. This particular version of the manual applies to most instances of the system, however you are urged to try and find a manual specific to your particular trial, as those are very likely to be less vague since the authors of these manuals knew of the particulars of the trial.

This manual is supposed to serve two distinct purposes: help users with the system if no specific documentation for their derivative of the system is available, and to serve as a template for a user's manual for implementors of the system. For this reason, and because *dardes* is most flexible, the manual is a bit more vague than one would expect.

# System Requirements

The requirements to use the *dardes* system are very modest. All that is needed is a properly configured web browser that allows access to the Internet. The operating system should be irrelevant. Supported web browsers are Firefox 2.x, Opera 9 and Internet Explorer 7. The browser must have SSL/TLS encryption support enabled. Newer or different browsers may work as well.

# Chapter 1

# General Usage

## 1.1 Logging in and out

Before using the system, all users are required to *log in*, or *authenticate*. This is to prevent unauthorised access to the system. Additionally, all modifications to any forms or other system data are kept in an electronic log. Among other things, the user name used to log in to the system is stored along with a record of the modifications.

Figure 1.1a shows the default log-in screen. This screen may look slightly different depending on the trial, usually bearing the logos of sponsors and relevant parties.

There are six important elements on this page:

**Mode** The *Mode* is where you decide which data set to use. Ordinarily you will simply choose the *Trial* mode, which is the real data set for the trial. Usually there is also a *Test Trial* mode, which is a sandbox of sorts with a separate data set. This latter mode is used to familiarise yourself with the system without jeopardising any of the real patient data.

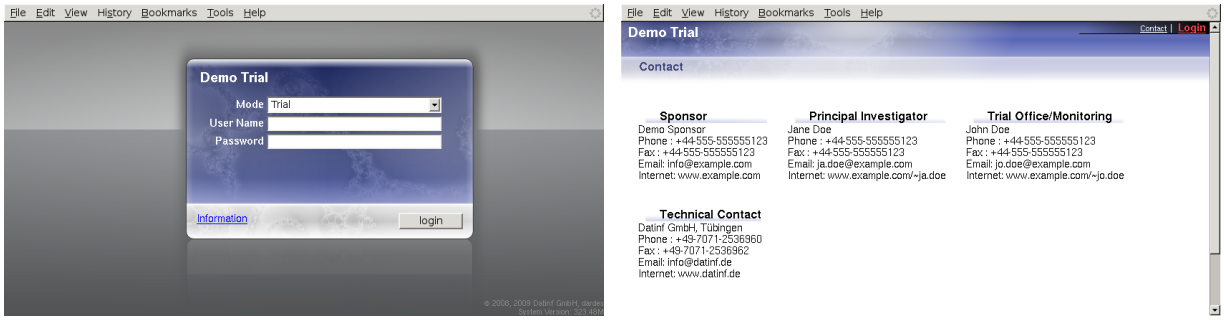
**User Name** This is the name you have been given as part of your user credentials. This identifies your *account*, complete with language settings and the contact details for inquiries. Each change you make to any data will have this name tacked on for auditors and monitors to see.

**Password** The other part of your user credentials. Input to this box will usually be hidden with asterisks or similar, to help against eavesdropping.

**Login Button** Click this (or hit the enter or return key on your keyboard) to submit your credentials. If the authorisation process is successful, you will be redirected to the *Home* page, otherwise you will be taken back here.

**Information Link** Following this link will lead you to a list of contacts responsible for this trial, as in figure 1.1b. Among others this includes a technical contact whom to contact in case you lose your user details.

**System Version** In case of bug reports or other issues, it is generally very helpful to provide this version to the developers.




(a) This is the authorisation page. Note the *System Version* that is displayed in the lower right corner of the screen.

(b) The types of contacts listed here may be slightly different, depending on whether you're logged in or not.

Figure 1.1: Authorisation and Contact Pages

## 1.2 General Navigation

All pages other than the authorisation page consist of a page header to the far top of the screen and the content area which occupies the remaining, lower portion of the screen. The other sections of this chapter generally explain the content area, whereas this section describes the header itself.

**Trial Name** The title on the top left indicates which trial you're currently participating in.

**Breadcrumbs** Below the trial name is a list of so-called 'breadcrumbs'. This form of navigation represents a trail of links you'd normally follow to get to the location you are at the moment. For example when viewing a form of a particular subject, you'll see trail elements such as 'home', 'subjects', 'subject NN' and the name of the form you're currently editing.

Clicking on any of these breadcrumbs will take you to that particular location.

**Links** The top right of the header contains a list of informative links, as well as the log-out button. Clicking any of the information links will display that information, using the logout button will cancel the currently active session so that the session ID may not be used for any further requests. You should always use the log-out function.

**User Details** The area on the right of the header contains information related to the currently authenticated user, i.e. the user's name, role and associated centre.

**Note** When logged into the system in 'test mode', there will be a big, red marker indicating that you are currently logged into a test mode instead of the real trial. This is to prevent anyone from inadvertedly randomising patients in this mode instead of the real trial mode.

**Automatic Log-out** Whenever any user of the system is inactive for longer than the amount of time configured for a specific trial (usually 20 minutes), the user is automatically logged out, to prevent others from gaining access to the system by examining the browser history, or similar methods.

## 1.3 The Home Page

Upon successfully logging in, you will be taken to the *Home* page, shown in figure 1.2. Here you will generally encounter two columns: on the left there is a list of things that may be done at the moment, on the right there is usually a brief protocol primer.

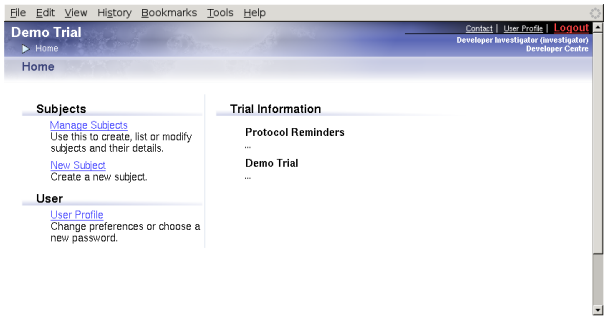



Figure 1.2: An overview of all the actions that may be performed at the moment.

**Subjects** The links in this paragraph allow manipulating the trial subjects to which you currently have access, i.e. all that are being treated in your centre.

**Manage Subjects** takes you to a list of subjects. The forms to fill out are accessible using this list, as are subjects that have not been randomised yet, in case the registration process of a new subject was not completed. See section 1.4 for more details.

**New Subject** will take you to a form that allows registering new subjects, as long as those meet the requirements for the trial. Randomisation is accessible as part of the registration process.

**User** This section encompasses settings related to your own profile.

**User Profile** is a link that takes you to the settings screen for your own profile. There you may change the interface language, among other things. See section 1.7 for more details.

**Trial Information** This is a free form paragraph, usually containing a primer on the trial protocol or possibly also including current status information or important things that need to be done. You will most likely have received a hard-copy version of all that is listed here.

Depending on the trial and your access rights, you may see additional elements on this page that were not described. Please refer to the manual for your particular trial for more information on these.

## 1.4 Managing Subjects

Whenever you choose the 'Manage Subjects' item, you will be presented with a list of all the currently registered subjects for this particular trial to which you currently have access to.

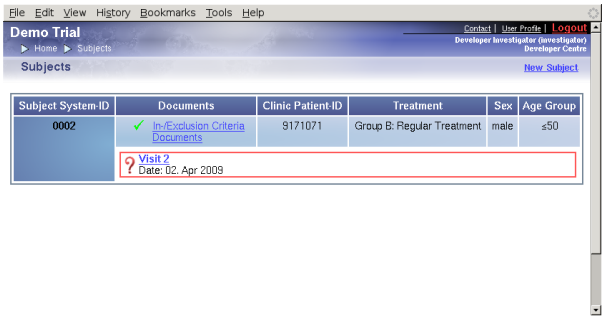



Figure 1.3: A list with all the current subjects.

This list is formatted as a table that contains all the basic information. To get access to all the documents (CRFs, etc) related to a subject, use the 'Documents' link in that particular subject's table row. There may also be a number of direct links to specific CRFs. These are formatted with a symbol to the left that indicates the current status. If this symbol is a red question mark, then that is usually an indication that the CRF is 'due', meaning that it has a 'date' field in the past and it hasn't been 'locked' yet. This feature was added to make sure that pre-dated CRFs that need to be filled out are easily accessible.

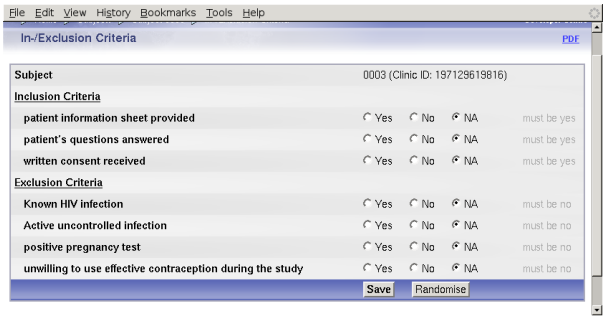
**Introducing new Subjects** On your home screen, choose the 'New Subjects' item from the list of actions, or alternatively, use the 'New Subjects' link as described in section 1.3. After clicking this link, you will be presented with an empty form, which needs to be filled out in order to create a new patient. The patient will not have been created until you successfully used the 'save' button, that is until there were no reported issues with the values you entered.

Subject creation will usually involve a 'Clinic Patient ID'. Any ID or mnemonic will do here, this is just to add some sort of context to the patient for reference by auditors, monitors or other staff members. You should not use anything sensitive, like the the patient's name or his or her social security number, which would give away the identity of the patient to anyone that would not otherwise have access to the patient's clinical records.

**Randomisation** Depending on the trial, there may be an option to 'randomise' subjects' trial groups. In these trials this process completely replaces the process of creating a new patient. To randomise a patient, you would go about as follows:

1. Click on "New Subject" on your home page or the subject list.
2. Fill in the form as appropriate.
   (a) If there is a "randomise" button, simply click it instead of "save" and the patient will be randomised.
   (b) Otherwise, click save and you will be taken to the form that allows randomisation, which you should then fill out and whose randomisation button you should use upon completion.
3. If randomisation is not possible, you will receive an error message describing why randomisation was not possible.
4. Once the subject is randomised, you will be taken to a summary page describing the subject's trial group and some other metadata. This is available from the subject's 'documents'.

**Note** All forms related to the randomisation process will automatically have been locked after the randomisation has completed successfully. This is to prevent tampering with the randomisation criteria.




(a) Form describing the different in- and exclusion criteria.

(b) This page is displayed after randomisation completes successfully. Take note of the treatment group.

Figure 1.4: Randomisation Form and Result

## 1.5 Forms, Visits, eCRFs

The term *Form* is used throughout the programme to describe an Electronic Case Report Form [eCRF]. This is also often called a "Visit", as this is what most forms are all about.

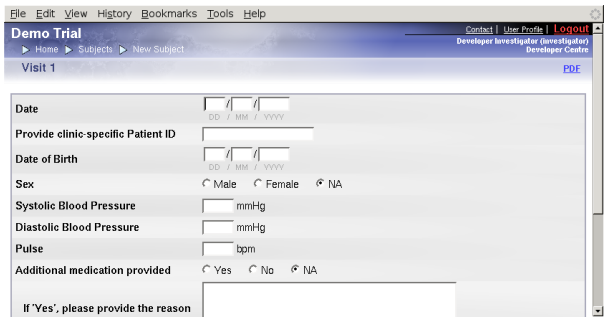



Figure 1.5: A visit; this is also often referred to as a *Form*, or an *eCRF*.

These forms, however, are also used in other places, such as 'Adverse Events' or even the user profile (See section 1.7).

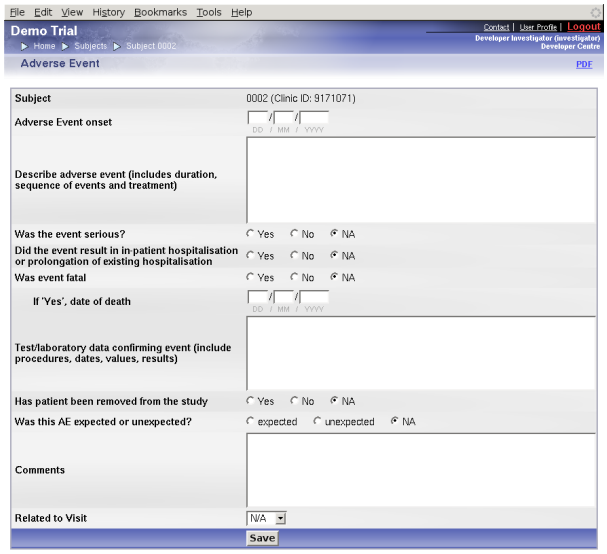

File Edit View History Bookmarks Tools Help
Demo Trial
Contact | User Profile | Logout
Home ▶ Subjects ▶ Subject 0002
Developer Investigator (investigator)
Developer Centre
Adverse Event
PDF
Subject
0002 (Clinic ID: 9171071)
Adverse Event onset
DD / MM / YYYY
Describe adverse event (includes duration, sequence of events and treatment)
Was the event serious?
Yes No NA
Did the event result in in-patient hospitalisation or prolongation of existing hospitalisation
Was event fatal
If 'Yes', date of death
Test/laboratory data confirming event (include procedures, dates, values, results)
Has patient been removed from the study
Was this AE expected or unexpected?
expected unexpected NA
Comments
Related to Visit
N/A
Save

Figure 1.6: A complete Form

There are a number of different areas of interest that are common to all forms. From top to bottom these are:

**The Title Bar** This is the area right below the header that is present on all pages. On the left you see the title of the current form ('Adverse Event') and on the right there is a list of possible export possibilies (e.g. 'PDF'). Clicking on the name of a format on the right will generate a version of the current form in that format.

**Form Contents** Next is a list of all the data related to the current form and the data that may be entered. The first item is usually a 'Patient ID', which cannot be modified.

Note that, when entering the data for your form, you should not use the 'enter' button on your keyboard to confirm individual bits of information. Hitting this button will submit the form as a whole to the server, and you may be redirected to some other form or page.

**Buttons** At the bottom of the page is usually a row of buttons, unless there is nothing that can be modified for the current form. In this example, there is only a 'Save' button. One of the buttons will have a bold font; this is the action that will be performed if you hit the enter key on your keyboard instead of clicking.

**Locking** It is very important that CRFs which you have completely filled out are 'locked'. This mechanism tells auditors and monitors that you think the data in this particular form is complete and correct, and it also tells the system that a form has been fully processed. In trials using the calendar feature, this controls the forms with the red question marks shown on the subject list.

To lock a form, simply either use the 'Lock' button, or check the 'Lock' checkbox and click on 'Save', whichever is shown on the form. This will prevent you from entering additional data, unless a trial monitor unlocks the form for you, for example if there is something missing.

**Exporting (e.g. to PDF)** Usually, you will be allowed to export the forms to a different format, e.g. for printing or archival. This is fairly easy to do: simply open up the form you wish exported and then click one of the links on the upper right, e.g. the 'PDF' link in the example above. Clicking that one would generate a file in the PDF format and automatically open it. You could then either save it or print it directly.

Do note that 'importing' of this data is not supported, so even though you will have a hardcopy, you cannot feed it back to the system.

**Issues** Trying to 'Save' a form with invalid data will result in a so-called 'issue'. These prevent the form from being saved, and a summary of the problematic data is shown. Some issues may be overridden,

**Common Data Types** A variety of data types may occur in any given form. The exact types that are available depend on the particular trial, but there are a number of types you will almost certainly encounter.

**Dates** This includes combinations of a year, month and day, possibly excluding the 'day' component. Date entry fields are localised, meaning the field arrangement depends on the language setting you chose in your profile. For example users that chose to use American English will be presented with the fields in MM/DD/YYYY order, whereas users of the British English language setting will see the fields in DD/MM/YYYY order. The server keeps track of the

actual date entered and properly arranges the data for each user, regardless of the format used to enter the data.

**Numerals** Either integers or decimals, depending on the particular form field. For integers, only digits and an optional sign are allowed. For decimals, only digits, an optional sign and either a dot or a comma are allowed.

Group markers, as in '1,000.00' or '1.000,00', are not allowed for either type of numeral, since they may easily be confused with the decimal separator, especially since both the dot and comma are allowed as separators.

**Text** Text entry fields, either single or multi-line. Anything is allowed here; special characters are automatically escaped, if necessary. In multi-line fields you may introduce line breaks with the 'enter' key on your keyboard.

**Multiple Choice** Multiple choice fields either use drop-down lists or a radio buttons. There is always an 'N/A' (Not Available) option, which is the default and indicates that no choice has been made, i.e. that the field has not been processed or cannot be processed.

## 1.6 The Calendar

In trials employing the calendar, trying to get to a subject's list of documents will automatiacally open the calendar view.

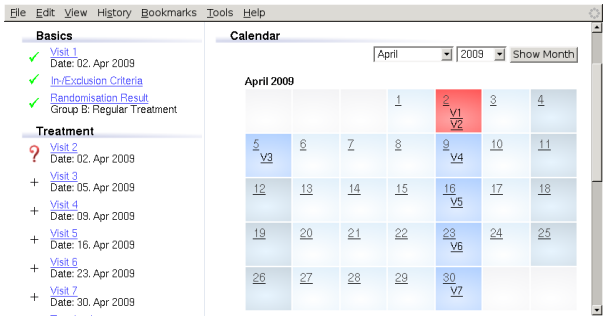



Figure 1.7: An excerpt from the calendar in the demo trial.

In this view, the area to the right of the page is generally reserved for the calendar, and the left contains a summary of all the forms for the chosen subject, as shown in figure 1.7. The forms in the summary have an icon code preceding them: a '✓' indicates forms that have been completed and properly locked, a red question mark indicates forms that have not been locked yet even though they are due, a thin plus is used for entries that have not been locked yet, or which have not been created yet, and which are not due in any way yet.

**Interacting with the Calendar** To see any of the forms for a specific day, simply click on the cell in the calendar. This will bring you to a list of things that happened on a particular day, and it may allow you to add additional details, i.e. forms, to that day.

This is primarily used for trials with a large number of forms per patient, or to add Adverse Events. For CRFs which may be added an arbitrary number of times, simply choosing the 'Create XXX' link in the day view will not create the form itself; instead you need to use the 'Save' button, as you needed to when creating a patient.

**Calendar Legend** Since trials usually employ different abbreviations and distinct CRFs, the calendar has a special calendar legend (see figure 1.8) that is linked from any page showing the calendar itself. This legend explains the abbreviations and the colour codes used in the calendar cells.

Usually, days that have any 'due forms', i.e. those with a date field in the past that have not been locked yet, are displayed in red, and days on a weekend are shown with a slightly darker shade. Thus red days in the calendar do not necessarily indicate an adverse event of any kind.

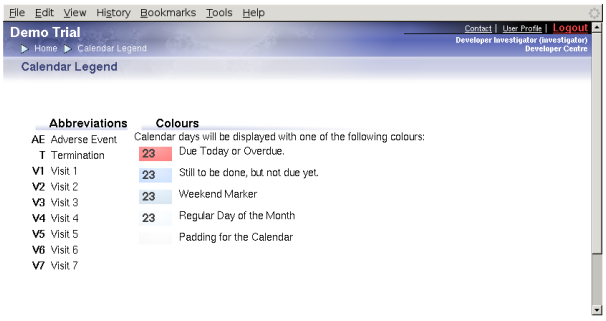



Figure 1.8: The calendar legend, listing colour assignments and abbreviations.

## 1.7 User Profile

The user profile allows users to change some of their personal details. Which details may be modified is up to the particular trial administration to decide, but in general you will be able to modify your password, language/localisation settings and your phone number

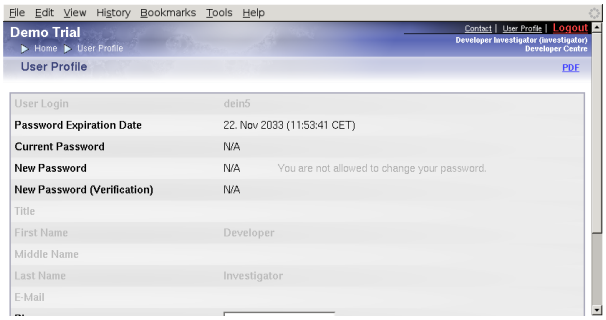



Figure 1.9: The user profile of a user in the demonstration trial.

**Password Expiration Date** This field indicates the day and exact time your password will become invalid. You will be notified of an imminent password expiration after $4/5$th of the time between last modification and maximum password liftime of a password for trial have passed, i.e. for a typical trial where passwords are valid for 90 days, you will be notified whenever you haven't modified your password for 72 days.

After the password has expired, the only action you may take upon logging in are profile modifications, until you change your password again. Trying to use any other page in the system will simply redirect you to this form.

**Current Password, New Password and Verification** To actually change your password, you need to confirm your current password, enter a new password that meets the requirements (displayed to the right of the 'New Password' field) and verify the new password by entering it a second time.

If the password has been changed successfully, you will be taken back to the log-in page to log in with the new details.

**Phone** You are allowed to modify the phone number listed here. This may be used by administrators, monitors or auditors to contact you in case there are any unresolved issues with some of the data you entered. You should keep this current.

**Note** You are not allowed to modify your e-mail address, because the system actively uses this on certain occasions. If you really need to change your e-mail address then you need to contact an administrator, or someone responsible for talking with the technicians.

**Language** In most trials you will be allowed to modify your own language settings. This setting will not only influence the language that is used in the user interface, but also certain spelling details, the date format used throughout the interface and which day the calendar starts on (thus the difference between British English and American English). Certain trials may make even more details dependant on the language setting.

# Chapter 2

# Special Details

## 2.1 Auditors

Auditors are supposed to verify that the data entered is correct and sound. They may not actively modify any data, but they are allowed to see preliminary statistics and they are allowed to decide which subjects are to be included and which aren't in the final results.

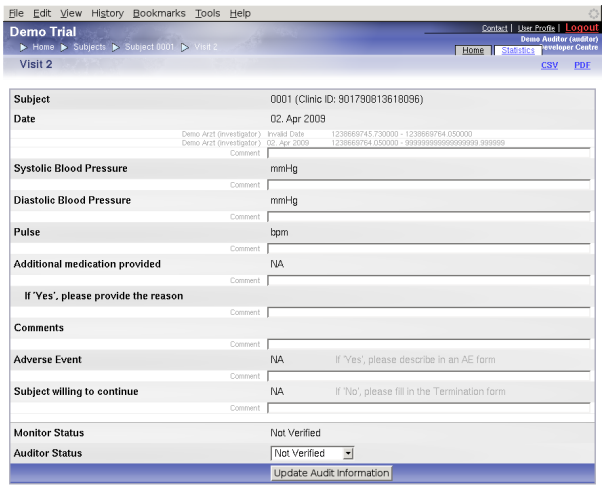



Figure 2.1: A typical form, as seen by an auditor.

**Audit Trail** Auditors (as well as monitors) are allowed to see the audit trails of forms. This includes any modification to any of the values, including a timestamp and the person modifying the field, and any comments added to a field by auditors or monitors.

**Comments** To add a comment to an arbitrary value, simply fill in its 'Comment' field and use the 'Save' or 'Update Audit Information' button.

**Form Audit Status** Auditors are allowed to set a status flag for each form. All of the forms start out with an audit status of 'not verified', which auditors may modify appropriately. Auditors are also allowed to read the anloguous status information set by monitors on a form.

**Statistics** On all pages an auditor will find a tab in the upper-right hand corner of the screen to switch to preliminary, 'live' statistics. These statistics are generated on the fly from the data in the database at the time of the request.

**Subject In-/Exclusion** In a subject's 'Documents', auditors find additional controls to in- or exclude a subject from the trial. In general all subjects start out as included, but they may be excluded from the final results, for example due to non-compliance with the trial protocol or premature terminal episodes.

**Limitations** Auditors may not create new patients, modify forms in any way (other than by adding audit information) or unlock forms for others to modify. Monitors, on the other hand, may do this.

## 2.2 Administrators

Administrators are not usually allowed to see most of the details that non-administators are allowed to see, but instead they are tasked with managing users, centres and access right distribution. However, any administrator could easily either grant her- or himself the right to view all the details that, for example a monitor is able to see, or create a new user with the appropriate role. In theory they could even change their own account's user role accordingly.

Due to the flexibility of the system, administrators may also grant other user groups parts of their own special privileges, such as creating users or centres, etc. It is also conceivable that there are special semi-administrator roles in larger trials dedicated to user management, for example.

Since administrators will usually be given the longer contractors' manual, there is no need to describe all aspects of their special access rights here.

## 2.3 Monitors

Monitors serve a very similar purpose to the auditors, except that they are allowed to actively modify form data.

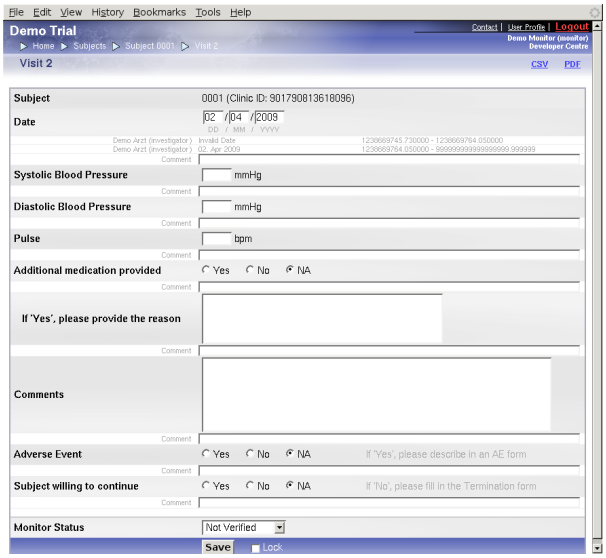



Figure 2.2: A typical form, as seen by a monitor.

**Forms** Just like auditors, monitors may see the audit trail and comment on current field values. Unlike monitors, however, they may change any form data and they are allowed to unlock previously locked forms, effectively allowing them to modify each and every regular CRF in the system.

**Form Monitor Status** Monitors have their own status information field for each and every form, analoguous to the audit status that auditors have.

**Limitations** Monitors may not view current live statistics, and they may not in- or exclude subjects from a trial. Additionally, they may not view the audit status set by an auditor, even though auditors may view the monitor status set by a monitor.

## 2.4 Troubleshooting

**Forms with red question marks** If you see a lot of these, even though you are certain that you have completed the form in question, bring it up and make sure you've also 'locked' the form.

**'No data available.' instead of the list of subjects** This is a warning message that only occurs before you register the first subject for your particular centre (or any centre in the case of a monitor account). If you're certain there are subjects registered with the trial, for example because you asked a someone else participating in the trial, then most likely that other person is registered with a different centre and you do not have sufficient access rights to see his or her subjects.

**Log In Issues** There are a number of reasons for this. The most obvious is that you can't remember your current account details. If that is the case, ask someone designated to talk with the technicians, or use the 'Information' link to find an appropriate technical contact.

Another reason for this is that the trial is currently locked. This would occur whenever software on the server is being updated, and typically you would be presented with a short notice describing when the programme will be back on-line on possibly also why it was taken offline in the first place.

Lastly, your account may have been deactivated. This may happen for various reasons, and the technical staff members that may deactivate accounts will not usually know the reason why an account was disabled, as this tends to be a decision made by the trial management. If you're certain that your account was disabled in error, you should thus contact your trial management contact, not members of the technical staff.

**Automatic Log-Out** The automatic log out feature is a very simple yet effective security feature. However, this feature does also incur a slight risk of data loss: if you've been filling out a form, and it takes you longer to complete the form than the time granted by the timeout, then once you click 'Save' you'll be logged out instead, and so the data is lost.

If the form really is too long to complete in the allotted time (20 minutes by default), one workaround is to complete the form 'incrementally', making sure to hit 'Save' before the timeout is complete and to then resume filling in the form.

Alternatively, if you already completed the form and you notice you've hit the timeout already (without the system telling you so), then you may try to open one of the links at the top of any page in a new window or tab, and then re-authenticating in that other window or tab. This would re-establish the current session, so you could then safely hit the 'Save' button on the original form.